SHIPPED: 2-2-54, from Albion, Mich., by Scientific Instrument Co.

LABEL IN PART: (Nameplate) "Ultrasonic The Scientific Instrument Compan Albion, Michigan U. S. A. Caution To Be Used By Or On The Prescriptio Of A Physician Only."

ACCOMPANYING LABELING: 2 booklets entitled "Operating Instructions for Elec trosonic Instrument," 16 reprints of an article from the Los Angeles Time entitled "Super-Sound Treatment Aids Arthritics, Hospital Says," 25 reprint of an article from Your Life Magazine of September 1952 entitled "Attackin Disease with Sound Waves," 14 reprints of an article from the May 1952 issue o The British Journal of Physical Medicine entitled "Prolapse of Intervertebra Discs Treated with Ultrasonic Waves," 24 reprints of an article from th February 18, 1952 issue of the New York Times entitled "Diseases Treated B Supersonic Aid," 23 reprints of an article from the June 1951 issue of Th British Journal of Physical Medicine entitled "Diseases of the Spine Treate With Ultrasonic Waves," 2 reprints of an article from the May 1952 issue o Postgraduate Medicine entitled "The Myofascial Genesis of Pain," 2 leaflet entitled "Latest Reports and Lectures of Scientific Papers on Ultrasonic Therapy," and 3 leaflets entitled "Investigate the New Electrosonic Sound Wav Instrument."

RESULTS OF INVESTIGATION: According to its label and accompanying labeling the device was intended for the production of ultrasonic energy for therapeutic use, but the operator was nowhere provided with information as to the frequency of the ultrasonic energy output and information as to the amount of ultrasonic energy given off by the device for the various settings of the output control mechanism. Since it was essential that the operator of the device be informed as to the frequency of the ultrasonic energy and the amount of ultrasonic energy output for the various settings of the output control mechanism, the labeling of the article did not bear information as to the use of the device as required by regulations.

LIBELED: 10-18-54, E. Dist. Wis.

CHARGE: 502 (f) (1)—the labeling of the article, when shipped, failed to bear adequate directions for use, and the article was not entitled to any exemption from that requirement.

DISPOSITION: 12-1-55; amended 12-20-55. Default—delivered to Food and Drug Administration.

5005. Hemovitameter device. (F. D. C. No. 39023. S. No. 51-480 M.)

QUANTITY: 1 *Hemovitameter device* bearing a segmented dial on which the segments were labeled with such designations as "digestion, blood, tissue, cell life," etc., at Albuquerque, N. Mex., in possession of Dr. S. C. Wyatt, D. C.

SHIPPED: During 1954, from Eckley, Colo., by Hemovitameter Laboratories, Inc.

ACCOMPANYING LABELING: Leaflet reading, in part, "To: Hemovitameter Co. Denver, Colo. * * * Vitality Element 66-4-8 general poison 59-2-7 inflamation 67-2-6 tissue degeneration."

RESULTS OF INVESTIGATION: The consignee placed in local newspapers advertisements by which the device was offered for use in obtaining information concerning various conditions which a person might have.

In actual use the consignee would have the patient take hold of two bars or electrodes that emerged from the device, and "readings" were taken which,

by reference to the dial and to the above-mentioned leaflet, were claimed to enable the consignee to determine the patient's condition.

LIBELED: 4–11–56, Dist. N. Mex.

CHARGE: 502 (a)—the labeling of the device, when shipped and while held for sale, contained false and misleading representations that the device was effective for diagnosing impaired digestion, abnormal conditions of the blood and tissues, the state of the body's cell life, the condition of the body's temperature regulating mechanism, the condition of the hair, teeth, eyes, and nails, the status of the iron balance in tissue digestion, the condition of one's bones, muscular functions, thyroid gland, brain, nerves, blood cell development, a condition of retarded growth, skin conditions, the condition of one's circulation and muscle function, abnormal tissue respiration, whether or not one requires a blood builder, a condition of general poisoning, inflammation, tissue degeneration, conditions due to bacterial toxins, a poisoned condition of the bowels, hyperacidic condition of the blood, conditions associated with excessive uric acid in the system, catarrh, streptococcus infection, staphlococcus infection, cancer, tuberculosis, conditions caused by excessive pressure on the nerves, sarcoma, ulcers, the state of one's glandular activity, calculi, anemia, fibroids, goiter, infestation by intestinal parasites, cysts, tumors, conditions due to scar tissue formation, rheumatism, cholelithiasis, eczema, and a toxic condition caused by excessive amounts of aluminum in the body.

502 (f) (1)—the labeling of the device, when shipped and held for sale, failed to bear adequate directions for use for diagnosing the conditions appearing in its labeling, since the labeling bore no directions for diagnosing such conditions, and it is impossible to devise adequate directions for such purposes and conditions. The labeling of the device failed also to bear adequate directions for use for obtaining information concerning one's heart action, nerve energy, the nature of one's ailments, the causes of one's ailments, and one's mineral and vitamin deficiencies, which were the conditions for which the device was intended and for which it was offered in the newspaper advertisements while held for sale.

DISPOSITION: 5–11–56. Default—delivered to Food and Drug Administration.

DRUGS FOR VETERINARY USE

5006. S–M capsules. (F. D. C. No. 38425. S. No. 15–560 M.)

QUANTITY: 1,156 boxes at Stockton, Calif., in possession of the Stockton Veterinary Supply Co.

SHIPPED: At various times from New York, N. Y.

LABEL IN PART: (Box) "Dr. Saunders * * * S–M Capsules Sodium Sulfamethazine Highly Recommended for Treating Many Bacterial Infections Contents: 6 Capsules * * * Directions: For Cattle and Horses: One Capsule for each 500 pounds of body weight. If necessary repeat every 24 hours until better."

RESULTS OF INVESTIGATION: The article had been shipped in powder form in bulk drums labeled, in part, "Sulfamethazine"; and, after its receipt by the consignee, the article was encapsulated and repacked into boxes labeled as described above.

Analysis showed that the article was sulfamethazine and not sodium sulfamethazine as declared on the box label.

LIBELED: 9–15–55, N. Dist. Calif.